Counting the Cost of Atrial Fibrillation

Use of Wireless Pacemaker Technology to Innovate Care Delivery

By Don McDaniel, MBA, Dan D’Orazio, MBA, and Brad Sutton, MD, MBA

Atrial Fibrillation (AF) impacts some 2.5 million adults in the U.S. and the incidence rate is expected to double over the next forty years. The disease burden of AF as measured in terms of mortality, morbidity and financial cost to the health care system is staggering. New strategies are needed to better manage AF. Wireless capable pacemakers offer a powerful solution to help improve care and mitigate the disproportionate resource consumption driven by AF.

Atrial Fibrillation’s Outsize Impact

Currently, 5% of the population consumes some 50% of all health care expenditures. Achieving both clinical and operational excellence will depend on identifying populations with the highest disease burden, hence, the highest costs, and proactively engaging these populations in health status improvement. Central to population health improvement lies cardiovascular disease (CVD), the leading cause of death in the United States. CVD constitutes 17% of domestic national health expenditures and by 2030, the total direct medical costs for CVD are expected to triple, going from $273 billion to $818 billion.

Atrial fibrillation, the most common cardiac rhythm abnormality, contributes significantly to CVD growth. Today, some 2.5 million American adults live with AF, the vast majority of whom are age 65 or older. Annual Medicare spending for newly diagnosed AF patients is currently estimated at $15.7 billion. Over the next 40 years, analysts project that the AF population will double, affecting nearly 5.6 million adults and driving a commensurate increase in Medicare spend.

While the direct costs of AF are significant and growing, the co-morbid conditions arising from AF serve as a cost multiplier. AF has been associated with an increased risk of stroke, dementia, heart failure (HF), and death. Exhibit 1 illustrates how AF disproportionately intersects with other cardiovascular diseases and stroke when compared to non-AF patients.

Role of AF Management in a Dynamic Payment Landscape

As the pendulum swings from a volume-based fee-for-service reimbursement system to one favoring value-based care, providers and health systems will increasingly need to focus on achieving health status improvements and total cost reduction. Historically, costs have been concentrated in institutional settings such as acute care facilities and emergency departments. Consider the following impact of AF on institutional settings:

1. Emergency room visits: Nearly 14% of AF patients (versus 3% of non-AF patients) had ≥ 3 emergency room visits during the first year post-AF diagnosis.
2. Hospital admissions: Approximately 28% of AF patients (versus 7% of non-AF patients) had ≥ 3 hospital admissions during the first year post-AF diagnosis. AF-related hospital admissions have increased by 60% in the last 20 years.
3. Readmissions: More than half (52%) of AF patients were readmitted to an inpatient hospital at least once within five quarters post-AF diagnosis, and 12% were admitted three times. AF was the primary diagnosis for 15% of these readmissions. Other readmission data demonstrates that 20% of hospital inpatient readmissions occurred within the first month following the first instance of an acute care hospitalization with an AF diagnosis on the claim. Of cardiac related readmissions, AF accounted for 31% of the diagnoses.

Today, leaders will be forced to more closely examine how they manage the preventative care of AF patients to avoid the disproportionate use of emergency room visits, hospital admissions and readmissions driven by the disease.
Higher Costs, Morbidity and Mortality: The Impact of AF on Pacemaker Patients

To further define the clinical and economic ramifications of AF, a retrospective claims analysis of Medicare data was conducted to compare the subset of pacemaker patients with AF to those without AF (19,945 cases). Costs and outcomes were calculated for the three years following implant, and “pacemaker-only” patients were segregated from “pacemaker/AF diagnosis” patients.

Consistent with other data sources, the retrospective analysis revealed that AF patients suffer substantially higher morbidity and mortality impact versus patients without AF. Specifically, pacemaker patients with AF were more likely (1.48 times) as pacemaker patients without AF to have stroke admissions, and twice as likely (2.03 times) to have congestive heart failure admissions. Additionally, the analysis revealed that over a three year period post pacemaker implant, mortality for pacemaker patients with AF was 35% compared to 28% for non-AF patients; thus, pacemaker patients with AF had mortality rates 26% greater than pacemaker patients without AF.

Health care expenditures for pacemaker patients, and specifically pacemaker patients with AF were high. While the prevalence of AF in the overall pacemaker population was 29%, the total health care spend was 35% higher on average for an AF patient compared to that of a non-AF patient. Based on the retrospective analysis (19,945 cases), the national expense burden of pacemaker patients (in three years post implantation) accounted for some $20.6 billion, with AF diagnosed pacemaker patients accounting for $7.3 billion of this total expenditure. Exhibit 2 reveals the higher overall health care costs for pacemaker patients with AF versus pacemaker patients with non-AF, and the percentage differences for each cost category.

Identifying AF with Prevention in Mind

Because of the linkages to costly and harmful complications, the early identification and management of AF has many potential benefits. Preventative AF efforts, however, need to be brought into sharper focus. As the American Heart Association notes, the “US health care system often rewards practices that treat disease and injury rather than those that prevent them.” Despite the desire to proactively identify AF, doing so can be elusive and challenging as it is often asymptomatic. A 2004 study by Israel et al. confirmed high levels of asymptomatic AF among patients implanted with sophisticated pacemakers capable of detecting recurrent AF. Asymptomatic AF, defined as lasting more than 48 hours, occurred in 17% of the patients studied and reoccurred in 16% of patients who had been “free” of AF for more than three months.

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A more recent market study, which surveyed 150 electrophysiologists (EP) and implanting cardiologists, supported Israel’s findings. Roughly 25% of physician respondents reported finding asymptomatic Atrial Tachycardia/Atrial Fibrillation (AT/AF) when they interrogated or checked the devices. With more than 75% of physicians reporting that they were “concerned” with asymptomatic AF, it remains an important issue requiring advanced solutions.

Deploying Wirelessly Enabled Pacemakers to Manage Atrial Fibrillation

The Atrial Fibrillation Reduction Atrial Pacing Trial (ASSERT), sponsored by St. Jude Medical and published in the January 12, 2012 edition of the New England Journal of Medicine, validated the critical importance of being able to identify subclinical or (asymptomatic) AF. ASSERT discovered that patients with subclinical atrial tachyarrhythmias were independently associated with a 2.5 factor increase in stroke or systemic embolism. As pacemakers have the ability to identify both symptomatic and asymptomatic AF, the value of the device is heightened if that data can be shared with the clinical team in a timely fashion.

Wireless pacemakers that are synchronized to remote patient management (RPM) systems enable daily data transmissions, with minimal requisite patient interaction, that can alert clinicians to AF events according to settings defined by the clinicians. Without a wireless pacemaker capable
of daily AT/AF monitoring, data may go unnoticed for significant periods of time before a clinician analyzes the data stored on the device during a follow-up visit. The CONNECT trial demonstrated the benefit of wireless monitoring in expediting clinical decisions. Specifically, CONNECT concluded that when compared to standard in-office follow-up, wireless remote monitoring with automatic clinician alerts greatly reduced the time to a clinical decision from 22 days in the traditional in-office check to 4.6 days for remote monitoring.

Despite this benefit, widespread adoption of wireless pacemakers has not yet reached a critical mass. According to the recent market study referenced above, only 47% of physicians reported using wireless pacemakers, yet 73% of physicians believe that it is important/very important to have wirelessly capable pacemakers. Since wireless enabled pacemakers allow physicians to have access to clinical data on a more timely basis in order to prevent health status decline, one must ask: What more can be done to drive the adoption of this technology to help detect and manage AF? This question deserves careful consideration in that, as was previously outlined, providing care for pacemaker patients with AF accounts for annualized incremental costs of $16,613 (or 35% greater spending) versus treating the non-AF patient.

Driving Patient Compliance

Actionable, precise clinical data serves as the bedrock for prevention, diagnosis, and treatment. Pacemakers are sensitive scientific instruments that can deliver on the promise of capturing precise data. However, elevating the power of the pacemaker requires an effort to move beyond simple data capture. Wirelessly transmitting that data to the care team through workflows that maximize patient compliance can help to ensure enhanced outcomes.

The St. Jude Medical portfolio of wireless pacemakers and their associated home monitoring workflows afford patients and clinicians with a unique opportunity to ensure a better care delivery process. St. Jude Medical is the sole device manufacturer with wireless pacemakers that can be “paired” with remote monitors immediately post-implant, either prior to hospital discharge or at the time of initial wound check (typically 7-10 days post implant). The timely ability to pair the device helps to educate the patient, removing technical objections, and results in an increased likelihood that the patient will utilize the home monitoring capability of the device. Other device manufacturers
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Concluding Implications

Atrial fibrillation is a rapidly growing problem, one that drives a disproportionate utilization of health services and one that negatively impacts health status. Wireless pacemakers and RPM systems possess an important, yet largely untapped ability to enable patients and clinicians to collaborate in efforts to stem the direct and indirect impact of AF.11 He notes that “if properly considered and deployed, it is quite possible to use technology to cut expenditures. Wireless access to data from the pacemaker is a perfect example of deploying technology to benefit the patient. In this case, the technology is already in place. It just needs to be put into use regularly.”

Though health care providers may have lacked solutions to proactively diagnose and manage AF, St. Jude Medical altered that equation with an industry leading wireless pacemaker and a technology-enabled workflow enhancement that allows pairing of the device at time of implant to a transmitter connected to an RPM system. Early identification of the presence of AF is critical in helping to ensure better health for affected patients and ultimately lower health care costs. Fortunately, the technology to achieve this goal of early AF diagnosis already exists.

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Brief Summary: Prior to using these devices, please review the instructions for use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

For more information, contact your local St. Jude Medical Representative.
sjprofessional.com/connectivity

REFERENCES

6. p <0.01 for heart failure, stroke, and acute myocardial infarction
7. The analysis used the Medicare 5% sample Limited Data Set Standard Analytical Files claims and enrollment data, identifying all pacemaker implants and revisions in the sample from the 2006 and 2007 calendar years (totaling 19,945 cases). Further, the analysis identified cases in which patients were alive in the quarter following the implant. The analysis included AF diagnoses identified at any point in the two quarters prior to implant and up to six quarters post-implantation.
8. The 5% LDS identified a sample size of 19,945 cases over a two year period (14,212 pacemaker cases, and 5,733 pacemaker cases with AF). To extrapolate the sample size for full population, the samples were multiplied by 20 to reflect 100 percent. Cost figures were then applied to arrive at the expenditures.
9. Note: Author's analysis of Medicare Sample 5% LDS Standard Analytical Files
11. Electrophysiology & Cardiology Survey, conducted online among 150 respondents (Electrophysiologists and Implanting Cardiologists) in the United States by In2ition, Inc., Jan 25 Feb 17, 2012. The double-blinded survey was funded by and is on file with St. Jude Medical.

typically ship the RPM equipment to the patient’s home, a process that can take up to a month and can result in significantly lower patient compliance. Sub-optimal compliance has been proven to undermine the ability of this technology to transmit data. For example, the CONNECT trial revealed that 45% of clinician alerts were never transmitted “mainly because the home monitor was not set up and initiated to send out transmission.”

Efforts aimed at maximizing patient compliance, like pairing the device with the home monitor in a care setting within days of implant as opposed to in the home many weeks later, offer common sense approaches to driving adoption. Interestingly, 77% of surveyed physicians agreed that patient compliance would improve if the home monitor were initiated immediately after implant.11

To gauge the impact of the capability to pair the home monitor before hospital discharge or at wound check, Kaiser Permanente studied patient compliance in the remote follow-up of St. Jude Medical cardiac implantable electronic devices.14 In this study, Kaiser enrolled 160 St. Jude Medical device patients from three centers. Patients in the control group were shipped a traditional home-based set-up, whereas patients in the intervention group received, at the time of their initial wound check, in-office instruction on use of the home monitor, had their device paired to the home monitor and were sent home with written instructions. The study results revealed that only 47% of patients in the control group adhered to remote follow-up. Conversely, 95% of patients in the intervention group (who had a St. Jude Medical device paired at the initial wound check) more than double the control group, successfully complied with remote monitoring. Christina Apostakos, RN X and Certified Cardiac Device Specialist who helped to lead the Kaiser Permanente study, noted that “the biggest impediment to taking full advantage of this great wireless pacemaker technology is the ability to get the device and the RPM system paired in a timely manner. If you cannot get the patient to connect to the Remote Patient Management system, valuable information from the device goes unreported. The ability to pair the device in the care setting proved invaluable in driving patient compliance.”

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